



4161-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0001]

Annual Public Meeting; Reagan-Udall Foundation for the Food and Drug Administration

AGENCY: Reagan-Udall Foundation for the Food and Drug Administration.

ACTION: Notice of annual meeting.

SUMMARY: The Reagan-Udall Foundation (the Foundation) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public meeting. The Foundation will discuss its activities and how it supports FDA.

DATES: The public meeting will be held on May 4, 2018, from 10 a.m. until 12 noon.

Registration to attend the meeting must be received by May 3, 2018, at 5 p.m. Eastern Time.

Requests for oral presentations must be received before May 2, 2018, at 5 p.m. Eastern Time.

See the SUPPLEMENTARY INFORMATION section for registration date and information.

The public is also invited to submit written comments by sending them via email to Elisabeth Shaefer (see FOR FURTHER INFORMATION CONTACT) before May 3, 2018, at 5 p.m.

Eastern Time.

ADDRESSES: The public meeting will be held at Alston & Bird, 950 F St., NW, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Elisabeth Shaefer, Executive Assistant to the Executive Director, Reagan-Udall Foundation for the FDA, 202-849-2255, eshaefer@reaganudall.org.

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit, organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation, and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research and engagement projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how the Foundation projects can help the Agency to fulfill its mission.

Foundation projects currently include: Innovation in Medical Evidence Development and Surveillance, a public-private partnership that allows researchers to study drug safety concerns of interest to public health; an Expanded Access Navigator that offers instructional material and resources for physicians, patients, and their caregivers on how to access investigational drugs outside of clinical trials; and a new joint Foundation and FDA regulatory science fellowship program.

II. Topics for Discussion at the Public Meeting

FDA Commissioner, Dr. Scott Gottlieb, will deliver a keynote address, followed by a panel discussion on the “Evolution of FDA Science and Engagement” and the role of the Foundation. Panelists will include the current FDA Commissioner, Dr. Scott Gottlieb, and

former FDA Commissioners Drs. Robert Califf and Andrew C. von Eschenbach. The panel moderator will be Susan Dentzer, President and Chief Executive Officer of the Network for Excellence in Health Innovation. Find the meeting agenda at <https://reaganudall.org/public-meeting>.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: <https://reaganudall.org/public-meeting>. Persons interested in attending this public meeting must register online by May 3, 2018, at 5 p.m. Eastern Time.

If you need special accommodations due to a disability, please contact Elisabeth Shaefer (see FOR FURTHER INFORMATION CONTACT) no later than May 1, 2018.

Requests for Oral Presentations: Interested persons may present comments at the public meeting. Comments will be scheduled to begin approximately at 11:30 a.m. Time allotted for comments may be limited to 3 minutes, dependent on the number of requests received. Those desiring to make oral comments should notify Elisabeth Shaefer (see FOR FURTHER INFORMATION CONTACT) by May 2, 2018. Please include a brief statement of the general nature of the comments you wish to present along with your name, address, telephone number, and email address. The contact person will notify individuals regarding their request to speak by May 3, 2018.

Dated: April 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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